

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Reinhold Schmieding

Application No.: 10/665,480

Confirmation No.: 5525

Filed: September 22, 2003

Art Unit: 3738

For: IMPLANT FOR CROSS-PIN ACL
RECONSTRUCTION (AS AMENDED)

Examiner: C. D. Prone

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under 37 C.F.R. § 41.37(a), this brief is filed within two months of the Notice of Appeal filed in this case on February 25, 2008, and is in furtherance of the Notice of Appeal.

The fees required under 37 C.F.R. § 41.20(b)(2) are addressed in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1205.2:

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| I. | Real Party In Interest |
| II | Related Appeals and Interferences |
| III. | Status of Claims |
| IV. | Status of Amendments |
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I. REAL PARTY IN INTEREST

The real party in interest for this appeal is Arthrex, Inc, a Delaware corporation, the assignee of this application.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 6 claims pending in application.

Claims 10-15 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claims 10, 11 and 13-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Grooms (Int. Application Pub. WO 99/21515) ("Grooms") in view of Chow (U.S. Patent No. 5,176,682).

Claim 12 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Grooms in view of Chow and further in view of Grooms et al. (U.S. Patent No. 6,045,554) ("Grooms '554").

B. Current Status of Claims

1. Claims canceled: 1-9
2. Claims withdrawn from consideration but not canceled: none
3. Claims pending: 10-15
4. Claims allowed: 0
5. Claims rejected: 10-15

C. Claims On Appeal

The claims on appeal are claims 10-15.

IV. STATUS OF AMENDMENTS

Applicant filed an Amendment After Final Rejection on January 23, 2008. The Examiner responded to the Amendment After Final Rejection in an Advisory Action mailed February 14, 2008. In the Advisory Action, the Examiner indicated that Applicant's proposed amendments to claims will not be entered. Accordingly, the claims enclosed herewith as Appendix A do not incorporate the amendment to claim 10 as set forth in the January 23, 2008 Amendment.

V. SUMMARY OF CLAIMED SUBJECT MATTER

In the discussion below, reference is made to the specification and drawings for exemplary embodiments of the invention covered by the claims. The specification and drawings references are not be considered as limiting the scope of the invention as defined by the claims.

The claimed invention relates to an implant for cross-pin anterior cruciate reconstruction surgery. (Application at ¶[0045]; Fig. 7A; reference character 40). According to claim 10 of the application, the implant comprises "a proximal end" and "a tapered distal end having a longitudinal axis and terminating in a pointed tip." (Application at ¶[0045]; Fig. 7A; reference character 42). The implant also comprises "a transverse eye for receiving a flexible strand to draw said implant into an opening in bone, said transverse eye extending completely through said tapered distal end in a direction transverse to the longitudinal axis of the distal end, said transverse eye communicating with longitudinal channels formed on opposite sides of the implant and extending completely from the transverse eye to the tip in a direction aligned with the longitudinal axis of the distal end." (Application at ¶[0045]; Fig. 7A; reference characters 46, 48). Claim 10 also recites "a solid cylindrical shaft disposed between, and extending completely from, said proximal end to said tapered distal end, said solid cylindrical shaft having a smooth cylindrical outer surface for supporting a graft in said opening in bone, the entire smooth cylindrical outer surface being parallel to a longitudinal axis of the shaft." (Application at ¶[0045]; Fig. 7A).

VI. GROUNDS OF REJECTION TO BE REVIEWED UNDER APPEAL

Whether the rejection of claims 10-15 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, should be reversed.

Whether the rejection of claims 10, 11 and 13-15 as being unpatentable over Grooms (Int. Application Pub. WO 99/21515) (“Grooms”) in view of Chow (U.S. Patent No. 5,176,682) should be reversed.

Whether the rejection of claim 12 as being unpatentable over Grooms in view of Chow and further in view of Grooms et al. (U.S. Patent No. 6,045,554) (“Grooms ‘554”) should be reversed.

VII. ARGUMENT

A. CLAIMS 10-15, AS AMENDED, COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT

Claims 10-15 are rejected under 35 U.S.C. § 112, as failing to comply with the written description requirement because claim 10, at lines 11 and 12, requires that the cylindrical shaft is “rigid,” and this feature is not supported in the specification. In response, applicant, on January 23, 2008, filed an Amendment deleting the term “rigid” from claim 10. Inexplicably, the Examiner refused to enter this Amendment. Since applicant has filed an amendment to delete this term from the claim, but the deletion has not occurred for procedural reasons (that are not clear to applicant), this issue is not ripe for appeal, unless the Examiner intends to maintain the rejection upon entry of the Amendment. The Examiner should indicate his intentions in this regard.

B. CLAIMS 10, 11 and 13-15 ARE PATENTABLE OVER GROOMS AND CHOW

Claims 10, 11 and 13-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Grooms (Int. Application Pub. WO 99/21515) (“Grooms”) in view of Chow (U.S. Patent No. 5,176,682). In the Office Action dated October 24, 2007 (“Final Rejection”), the Examiner asserts that “Grooms discloses the invention substantially as claimed being an implant shown in figure 2B comprising a blunt proximal end (202), a tapered distal end adapted to receive a suture (201), a transverse eye (210), and a cylindrical shaft (204).” (Final Rejection at 3). The Examiner admits that “Grooms fails to teach the use of channels formed on opposite sides of the implant while maintaining the shafts (sic) cylindrical outer shape” but asserts that “[I]t would have been obvious to one having ordinary skill in the art . . . [to] use the tapered channels surrounding the through hole

taught by Chow on the implant of Grooms in order to provide an implant that has a smoother guide surface for the suture thread around the through hole.” (Final Rejection at 3). This rejection is respectfully traversed.

Independent claim 10 recites an “implant for cross-pin anterior cruciate reconstruction surgery” comprising *inter alia* “a proximal end,” “a tapered distal end having a longitudinal axis and terminating in a pointed tip” and “a transverse eye for receiving a flexible strand to draw said implant into an opening in bone, said transverse eye extending completely through said tapered distal end in a direction transverse to the longitudinal axis of the distal end, said transverse eye communicating with longitudinal channels formed on opposite sides of the implant and extending completely from the transverse eye to the tip in a direction aligned with the longitudinal axis of the distal end.” Independent claim 10 also recites “a solid cylindrical shaft disposed between, and extending completely from, said proximal end to said tapered distal end, said solid cylindrical shaft having a smooth cylindrical outer surface for supporting a graft in said opening in bone, the entire smooth cylindrical outer surface being parallel to a longitudinal axis of the shaft.”

Dependent claim 11 recites that “the implant is formed of allograft bone.” Dependent claims 13-15 recite that “the transverse eye of the tapered distal end is adapted to receive a flexible strand comprising suture” (claim 13), that “the channels are configured to accommodate the suture received in the eye of the implant to prevent binding of the suture as the implant is inserted into the bone” (claim 14), and that “the proximal end of the implant is blunt” (claim 15).

The subject matter of claims 10, 11 and 13-15 would not have been obvious over Grooms and Chow for at least two reasons: (i) the cited prior art references do not disclose or suggest all limitations of claims 10, 11 and 13-15; and (ii) a person of ordinary skill in the art would not have been motivated to combine the cited prior art references, to arrive at the claimed subject matter.

1. THE CITED PRIOR ART REFERENCES DO NOT DISCLOSE OR
SUGGEST ALL LIMITATIONS OF THE CLAIMED INVENTION

The cited references, considered alone or in combination, simply do not disclose or suggest all limitations of claims 10, 11 and 13-15. None of Grooms and Chow discloses or suggests “a transverse eye . . . communicating with longitudinal channels formed on opposite sides of the implant and extending completely from the transverse eye to the tip,” as claim 10 recites.

Grooms does not disclose or illustrate any channels in communication with an eye, much less in communication with a transverse eye. Chow is cited as disclosing channels, but Chow does not disclose or suggest channels “extending completely from the transverse eye to the tip.” Chow is also silent about “a tapered distal end.”

In the Final Rejection, the Examiner asserts that “[I]t would have been obvious . . . [to] use the tapered channels surrounding the through hole taught by Chow on the implant of Grooms” (Final Rejection at 3). This assertion is incorrect. First, Chow does not disclose any implant with a “through hole.” Surgical implement 10 of Chow is provided with fins 16a, 16b and a recess 18 to allow ligament L to be caught in the recess 18 before insertion into a hole. However, recess 18 of Chow is not a “through hole” or an “eye” provided through a “tapered distal end” and is not “extending completely through said tapered distal end,” as in the claimed invention. Because of its configuration (designed specifically for ligament positioning), the recess 18 of Chow is also not a “transverse eye,” much less a “transverse eye for receiving a flexible strand,” or a “transverse eye for receiving a flexible strand to draw said implant into an opening in bone,” as claim 10 recites.

Second, channels 20a, 20b of Chow are clearly not “extending completely from the transverse eye to the tip.” These channels are not in communication with a transverse eye and, thus, they cannot be extending from a transverse eye to the tip of the implant. Thus, even if *arguendo* Grooms teaches an eye and even if *arguendo* Chow teaches longitudinal channels, the combined references still do not disclose or suggest an eye with channels “extending completely from the transverse eye,” as in the claimed invention.

The cited references also fail to disclose or suggest an implant with “a transverse eye . . . communicating with longitudinal channels formed on opposite sides of the implant and extending completely from the transverse eye to the tip” and further “formed of allograft bone” (claim 11) or that “the transverse eye of the tapered distal end is adapted to receive a flexible strand comprising suture” (claim 13). Grooms and Chow, alone or in combination, are also silent about an implant as recited in claim 10 and further with the channels “configured to accommodate the suture received in the eye of the implant to prevent binding of the suture as the implant is inserted into the bone” (claim 14). Channels 20a, 20b of Chow allow a ligament to be captured within recess 18, and are not configured to accommodate suture that is received in the transverse eye and that extends from the eye to the tip of the implant through longitudinal channels.

The cited references also fail to disclose or suggest an implant with “a transverse eye . . . communicating with longitudinal channels formed on opposite sides of the implant and extending completely from the transverse eye to the tip” and further that “the proximal end of the implant is blunt” (claim 15).

2. NO MOTIVATION TO COMBINE THE REFERENCES EXISTS

Applicants further submit that one skilled in the art would not have been motivated to combine the teachings of Grooms (regarding an “eye”) with those of Chow (regarding a “channel”). Grooms relates to a bone implant having a rigid, mineralized bone segment, and a flexible, demineralized segment formed by exposing the implant to a HCl solution, for example. Grooms teaches that the demineralized segment has “sufficient flexibility to act as a ligament, tendon, or flexible support” (claim 3). In contrast, the crux of Chow is a surgical implement 10 provided with fins 16a, 16b and a recess 18 (to allow ligament L to be caught in the recess 18 before insertion into a hole) and also provided with a central bore 14 (to allow hollow tool T to matingly engage implement 10 to force the fins 16a, 16b outwardly against the sidewalls of the hole). Accordingly, one skilled in the art would not have been motivated to combine the bone implant of Grooms, which has a demineralized segment that itself acts as a ligament or tendon between two body parts, with the surgical implement 10 of Chow, which is specifically designed to retain a ligament and which has a configuration (with a central bore that allows a tool to engage the implement) that allows it to

rotate within a hole. One skilled in the art would also not have been motivated to combine the demineralized/mineralized bone segments of Grooms with the surgical implement of Chow provided with flexible fins that are “forced outwardly” into the bone hole, as the demineralized/mineralized bone segments of Grooms would not withstand any force exerted by such fins.

In view of the above, the Office Action fails to establish a *prima facie* case of obviousness, and reversal of the rejection of claims 10, 11 and 13-15 is respectfully requested.

**B. CLAIM 12 IS PATENTABLE OVER GROOMS IN VIEW OF CHOW,
AND FURTHER IN VIEW OF GROOMS ‘554**

Dependent claim 12 depends on independent claim 10 and recites that “the implant is formed of synthetic bone material.”

The subject matter of claim 12 would not have been obvious over Grooms, Chow and Grooms ‘554, whether considered alone or in combination. The cited references do not disclose or suggest all limitations of independent claim 10 and of dependent claim 12. As noted above, Grooms and Chow are silent about “a transverse eye . . . communicating with longitudinal channels formed on opposite sides of the implant and extending completely from the transverse eye to the tip,” as claim 10 recites. As also noted above, a person of ordinary skill in the art would also not have been motivated to combine the teachings of Grooms with those of Chow, to arrive at the claimed subject matter.

Grooms ‘554 fails to address the deficiencies of Grooms and Chow. Grooms ‘554 is silent about any of the limitations of claims 10 and 12. Grooms ‘554 teaches an interference screw formed from a machined fragment of cortical bone with about 75-95% of its length covered by threads, and not an “implant for cross-pin anterior cruciate reconstruction surgery” having “a transverse eye for receiving a flexible strand to draw said implant into an opening in bone, said transverse eye extending completely through said tapered distal end in a direction transverse to the longitudinal axis of the distal end,” as claim 10 recites.

A person skilled in the art would further not have been motivated to combine the demineralized/mineralized bone segments of Grooms with the screw of Grooms '554, which is covered for about its entire length with threads and also provided with a square or hexagonal head (to allow engagement of a screw-driving implement) that is comparable to a metallic interference screw.

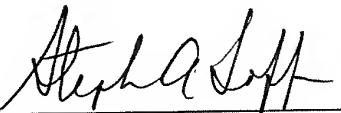
For at least the reasons above, the Office Action fails to establish a *prima facie* case of obviousness, and reversal of the rejection of claim 12 is also respectfully requested.

VIII. CONCLUSION

Claims 10-15, as amended in the unentered Amendment of January 23, 2008, comply with the requirements of 35 U.S.C. § 112, first paragraph. The Examiner's rejection of claims 10-15 on prior art grounds should be reversed for the reasons set forth above.

Dated: April 24, 2008

Respectfully submitted,

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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 10/665,480:

Claims 1-9. (Canceled)

10. (Previously presented) An implant for cross-pin anterior cruciate reconstruction surgery, comprising:

a proximal end;

a tapered distal end having a longitudinal axis and terminating in a pointed tip;

a transverse eye for receiving a flexible strand to draw said implant into an opening in bone, said transverse eye extending completely through said tapered distal end in a direction transverse to the longitudinal axis of the distal end, said transverse eye communicating with longitudinal channels formed on opposite sides of the implant and extending completely from the transverse eye to the tip in a direction aligned with the longitudinal axis of the distal end; and

a solid rigid cylindrical shaft disposed between, and extending completely from, said proximal end to said tapered distal end, said solid rigid cylindrical shaft having a smooth cylindrical outer surface for supporting a graft in said opening in bone, the entire smooth cylindrical outer surface being parallel to a longitudinal axis of the shaft.

11. (Previously presented) The implant of claim 10, wherein the implant is formed of allograft bone.

12. (Previously presented) The implant of claim 10, wherein the implant is formed of synthetic bone material.

13. (Previously presented) The implant of claim 10, wherein the transverse eye of the tapered distal end is adapted to receive a flexible strand comprising suture.

14. (Previously presented) The implant of claim 13, wherein the channels are configured to accommodate the suture received in the eye of the implant to prevent binding of the suture as the implant is inserted into the bone.

15. (Previously presented) The implant of claim 10, wherein the proximal end of the implant is blunt.

APPENDIX B

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered by or relied upon by the examiner is being submitted.

APPENDIX C

No related proceedings are referenced in II. above, hence copies of decisions in related proceedings are not provided.